UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF TEXAS
HOUSTON DIVISION

MICHAEL R. STANFIELD,	§	
	§	
Plaintiff,	§	
VS.	§	CIVIL ACTION NO. 4:15-CV-414
	§	
BOSTON SCIENTIFIC CORPORATION, *et al*,	§	
	§	
	§	
Defendants.	§	

OPINION AND ORDER OF DISMISSAL

Pending before the Court in the above referenced strict liability and negligence action, removed from state court on diversity jurisdiction and seeking damages for injury suffered because of the implantation of an allegedly negligently designed, manufactured, and marketed BSC ADVANTIO DR IS pacemaker, Model K063, serial number 124393, and a Guidant DEXTRUS IS-1 right ventricular ("RV") lead, Model 29107536, is Defendants Boston Scientific Corporation ("BSC") and Guidant LLC's ("Guidant's")[1] motion to dismiss pursuant to Rule 12(b)(6) (instrument #4). The Original Petition (#1, Ex. B) asserts state-law claims for product liability, including negligence, strict liability, breach of express and implied warranties, and failure to warn. Plaintiff Michael R. Stanfield ("Stanfield"), although represented by counsel, has failed to file a response.

BSC and Guidant contend that the Court should dismiss Stanfield's suit because (1) federal law preempts all of his state-law claims and (2) under Federal Rule of Civil Procedure 12(b)(6) because he fails to plead facts sufficiently to state a claim under applicable United

[1] Defendants state that Plaintiff's Original Petition misstates Guidant LLC's name as "Guidant Corporation." They explain that Guidant LLC formerly did business as Guidant Corporation, but that on February 19, 2012 it converted into Guidant LLC under Indiana law. #4, p. 1. n.1.

States Supreme Court precedent.

Background

According to the Original Petition, after suffering from sick sinus syndrome and chest pain and after hearing noise coming from his pacemaker, Stanfield had surgery on January 26, 2013 for a rescission of a pacemaker generator and extraction of a RV lead. The surgeon found that the RV lead had a marked insulation break, which he freed up, and then extracted the RV lead.[2]

The Original Petition charges Defendants with strict liability for negligently designing, selecting parts and materials for, developing, manufacturing, assembling, packaging, testing, advertising, promoting, marketing, and selling the pacemaker, model no. K063, serial no. 124393, and the RV lead, Guidant model no. 4136, serial no. 29107536, in a defective and unreasonably dangerous condition and design. Stanfield also alleges that BSC and Guidant breached their express and implied warranties that the pacemaker and RV lead were safe, merchantable, and fit for use.

Standard of Review

Federal Rule of Civil Procedure 8(a)(2) provides, "A pleading that states a claim for relief must contain . . . a short and plain statement of the claim showing that the pleader is entitled to relief." When a district court reviews a motion to dismiss pursuant to Fed. R. Civ. P. 12(b)(6), it must construe the complaint in favor of the plaintiff and take all well-pleaded facts as true. *Randall D. Wolcott, MD, PA v. Sebelius*, 635 F.3d 757, 763 (5th Cir. 2011), *citing Gonzalez v. Kay*, 577 F.3d 600, 603 (5th Cir. 2009). The plaintiff's legal conclusions are not entitled to the

[2] Defendants explain, "The leads are thin, insulated wires that connect the pulse generator, which is the power source of the pacemaker, to either the surface or inside of the heart. Leads carry electrical signals between the heart and the pulse generator." #4, p. 2, n.2.

same assumption. *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009)("The tenet that a court must accept as true all of the allegations contained in a complaint is inapplicable to legal conclusions."), *citing Bell Atlantic Corp. v. Twombly*, 556 U.S. 662, 678 (2007); *Hinojosa v. U.S. Bureau of Prisons*, 506 Fed. Appx. 280, 283 (5th Cir. Jan. 7, 2012).

"While a complaint attacked by a Rule 12(b)(6) motion to dismiss does not need detailed factual allegations, . . . a plaintiff's obligation to provide the 'grounds' of his 'entitle[ment] to relief' requires more than labels and conclusions, and a formulaic recitation of the elements of a cause of action will not do . . . ." *Bell Atlantic Corp. v. Twombly*, 127 S. Ct. 1955, 1964-65 (2007)(citations omitted). "Factual allegations must be enough to raise a right to relief above the speculative level." *Id.* at 1965, *citing* 5 C. Wright & A. Miller, *Federal Practice and Procedure* § 1216, pp. 235-236 (3d ed. 2004)("[T]he pleading must contain something more . . . than . . . a statement of facts that merely creates a suspicion [of] a legally cognizable right of action"). "*Twombly* jettisoned the minimum notice pleading requirement of *Conley v. Gibson*, 355 U.S. 41 . . . (1957)["a complaint should not be dismissed for failure to state a claim unless it appears beyond doubt that the plaintiff can prove no set of facts in support of his claim which would entitle him to relief"], and instead required that a complaint allege enough facts to state a claim that is plausible on its face." *St. Germain v. Howard*,556 F.3d 261, 263 n.2 (5th Cir. 2009), *citing In re Katrina Canal Breaches Litig.*, 495 F.3d 191, 205 (5th Cir. 2007)("To survive a Rule 12(b)(6) motion to dismiss, the plaintiff must plead 'enough facts to state a claim to relief that is plausible on its face.'"), *citing Twombly*, 127 S. Ct. at 1974). "'A claim has facial plausibility when the pleaded factual content allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged.'" *Montoya v. FedEx Ground Package System, Inc.*, 614 F.3d 145, 148 (5th Cir. 2010), *quoting Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009).

The plausibility standard is not akin to a "probability requirement," but asks for more than a "possibility that a defendant has acted unlawfully." *Twombly*, 550 U.S. at 556. Dismissal is appropriate when the plaintiff fails to allege "'enough facts to state a claim to relief that is plausible on its face'" and therefore fails to "'raise a right to relief above the speculative level.'" *Montoya*, 614 F.3d at 148, *quoting Twombly*, 550 U.S. at 555, 570.

In *Ashcroft v. Iqbal*, 556 U.S. at 679, the Supreme Court stated that "only a complaint that states a plausible claim for relief survives a motion to dismiss," a determination involving "a context-specific task that requires the reviewing court to draw on its judicial experience and common sense." "[T]hreadbare recitals of the elements of a cause of action, supported by mere conclusory statements do not suffice" under Rule 12(b). *Iqbal*, 129 S. Ct. at 1949. The plaintiff must plead specific facts, not merely conclusory allegations, to avoid dismissal. *Collins v. Morgan Stanley Dean Witter*, 224 F.3d 496, 498 (5th Cir. 2000). "Dismissal is proper if the complaint lacks an allegation regarding a required element necessary to obtain relief . . . ." *Rios v. City of Del Rio, Texas*, 444 F.3d 417, 421 (5th Cir. 2006), *cert. denied*, 549 U.S. 825 (2006).

"Rule 12(b) is not a procedure for resolving contests about the facts or the merits of a case." *Gallentine v. Housing Authority of City of Port Arthur, Tex.*, __ F. Supp. 2d __, Civ. A. No. 1:12-CV-417, 2013 WL 244651, *3 (E.D. Tex. Jan. 22, 2012), *citing* 5A Charles A. Wright & Arthur R. Miller, *Federal Practice and Procedure: Civil 2d* § 1356, at 294 (1990).

As noted, on a Rule 12(b)(6) review, although generally the court may not look beyond the pleadings, the Court may examine the complaint, documents attached to the complaint, and documents attached to the motion to dismiss to which the complaint refers and which are central to the plaintiff's claim(s), as well as matters of public record. *Lone Star Fund*

V (U.S.), L.P. v. Barclays Bank PLC, 594 F.3d 383, 387 (5th Cir. 2010), *citing Collins*, 224 F.3d at 498-99; *Cinel v. Connick*, 15 F.3d 1338, 1341, 1343 n.6 (5th Cir. 1994). *See also United States ex rel. Willard v. Humana Health Plan of Tex., Inc.*, 336 F.3d 375, 379 (5th Cir. 2003)("the court may consider . . . matters of which judicial notice may be taken"). Taking judicial notice of public records directly relevant to the issue in dispute is proper on a Rule 12(b)(6) review and does not transform the motion into one for summary judgment. *Funk v. Stryker Corp.*, 631 F.3d 777, 780 (5th Cir. 2011). "A judicially noticed fact must be one not subject to reasonable dispute in that it is either (1) generally known within the territorial jurisdiction of the trial court or (2) capable of accurate and ready determination by resort to sources whose accuracy cannot reasonably be questioned." Fed. R. Evid. 201(b).

Substantive Law

The Medical Device Amendments Act of 1976 ("MDA"), 21 U.S.C. § 360k, to the Federal Food, Drug, and Cosmetics Act ("FDCA"), 21 U.S.C. § 352, *et seq.*, established a scheme of detailed federal oversight for three classes of medical devices intended for human use, with "the degree of regulations thought necessary to provide reasonable assurance of each device's 'safety and effectiveness'" depending on the device's classification and restricted state oversight, which previously had largely regulated new medical devices. *Ivy Sports Medicine LLC v. Burwell*, 767 F.3d 81, 83 (D.C. Cir. 2014); *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 315-16 (2008). Class III devices receive the greatest federal oversight. *Riegel*, 552 U.S. at 317; *Bass v. Stryker Corp.*, 669 F.3d 501, 506 (5th Cir. 2012). Class III devices either "presen[t] a potential unreasonable risk of illness or injury" or are "for a use in supporting or sustaining human life or for a use which is of substantial importance in preventing the impairment of human health." *Hughes v. Boston Scientific Corp.*, 631 F.3d 762, 764 (5th Cir. 2011), *citing* 21 U.S.C. §

360c(a)(1)(C). Manufacturers of Class III devices must provide evidence to the FDA that such devices are both safe and effective. *Id., citing* § 360e(d)(2). The MDA was passed by Congress to regulate medical devices and expressly preempt certain state regulations because state law governance of medical devices was seen as inadequate. *Bass*, 669 F.3d at 506, *citing Riegel*, 552 U.S. at 315-16.

The MDA included the following express preemption provision, 21 U.S.C. § 360k(a):

> Except as provided in subsection (b) of this section, no State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement–
>
> > (1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and
> >
> > (2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement[3] applicable to the device under this chapter.

Section 360k does not bar a state from making a damages remedy available for claims based on a violation of FDA regulations because in that kind of case, the state duties "'parallel,' rather than add to, federal requirements.'" *Riegel*, 552 U.S. at 330. Thus a state-law tort claim for injury purportedly suffered because of a medical device is preempted if (1)"'the Federal Government has established requirements applicable to [the device]; and (2) the claims are based on state law safety and (3) the claims are based on state law requirements that are different from, or in addition to the federal ones, and that relate to safety and effectiveness.'" *Rodriguez v. Am. Medical Systems, Inc.*, 597 Fed. Appx. 226, 228 (5th Cir. Dec. 31, 2014), *quoting Bass*, 669 F.3d

[3] "Requirement" as used in this provision includes state common law tort actions. *Riegel*, 552 U.S. at324-25.

at 507, *citing Riegel*, 552 U.S. at 321-22 (after his coronary artery ruptured during surgery, plaintiff sued Medtronic, Inc. for strict liability, negligence, and breach of express and implied warranties, asserting that the balloon catheter used was defectively designed, labeled, manufactured, sold and distributed in ways that violated New York's common law; the Supreme Court held that the state common law claims were preempted because they imposed requirements "different from, or in addition to" requirements imposed by federal law).[4]

Because the MDA preempts state requirements only where they are "different from, or in addition to" federally imposed requirements, the Supreme Court did hold that "parallel" state claims for violations of federally imposed requirements, are not preempted by § 360k. *Riegel*, 552 U.S. at 330, *citing Lohr*, 518 U.S. at 495.

The pacemaker and lead at issue here were classified by the United States Food and Drug Administration ("FDA") as Class III Medical Devices and were approved by its rigorous premarket approval ("PMA")[5] and Product Development Protocol (PDP)[6]processes.

---

[4] Since the catheter had PMA approval, the Supreme Court reasoned that state common law could impose more stringent requirements than those imposed by federal regulation for marketing it.

[5] As described by the Supreme Court in *Riegel*, 552 U.S. at 31-18,

> Premarket approval is a "rigorous" process. A manufacturer must submit what is typically a multivolume application. . . . It includes, among other things, full reports of all studies and investigations of the device's safety and effectiveness that have been published or should reasonably be known to the applicant; a "full statement" of the device's "components, ingredients and properties, and of the principle or principles of operation"; "a full description of the methods used in, and the facilities and controls used for, the manufacture, processing, and, when relevant, packing and installation of, such device'; samples or device components required by the FDA; and a specimen of the proposed labeling. § 360e(c)(1). Before deciding whether to approve the application, the agency may refer it to a panel of outside experts, 21 CFR § 814.44(a)(2007), and may request additional data from the

The FDA's approval is a matter of public record under both processes, and thus the Court may

> manufacturer. § 360e(c)(1)(G).

If the FDA gives premarket approval,

> the MDA forbids the manufacturer to make, without FDA permission, changes in design specifications, manufacturing processes, labeling, or any other attribute, that would affect safety or effectiveness. § 360e(d)(6)(A)(I). If the applicant wishes to make such a change, it must submit, and the FDA must approve, an application for supplemental premarket approval, to be evaluated under largely the same criteria as an initial application.

Id. at 319. PMA includes review of the device's proposed labeling to determine its safety and effectiveness under the conditions set forth on the label and if it is false or misleading. *Id.* at 319; §§ 360c(a)(2)(B) and 360e(d)(1)(A).

After a device is granted PMA, the manufacturer cannot modify the product's specifications, process, or label without further approval. § 360e(d)(6)(A)(I). In addition, there are numerous reporting requirements under § 360i, including new clinical investigations or scientific studies and reports of incidents in which the device may have caused or contributed to death or serious injury or malfunctioned. *Id.* The FDA can withdraw PMA at any time that it determines the device to be unsafe or ineffective under its labeling. §§ 360e(e)(1) and 360h(e). *Id.* at 319-20.

> [6] A PDP applicant must provide
>
> (1) a description of the device and the changes which may be made in the device;
> (2) a description of the preclinical trials (if any) of the device . . . ;
> (3) a description of the clinical trials (if any) of the device . . .;
> (4) a description of the methods to be used in, and the facilities and controls to be used for, the manufacture, processing and, when relevant, packing and installation of the device;
> (5) an identifying reference to any device;
> (6) if appropriate, specimens of the labeling proposed to be used for the device;
> (7) such other information relevant to the subject matter of the protocol as the Secretary with the concurrence of the appropriate panel or panels . . . may require; and
> (8) a requirement for submission of progress reports and, when completed, records of the trials conducted under the protocol, which records are adequate to show compliance with the protocol.

Betterton v. Evans, 351 F. Supp. 2d 529, 534-35 (N.D. Miss. 2004), *citing* 21 U.S.C. § 360e(f)(3)(B)(i)-(viii).

take judicial notice of it as a matter of public record. *See* 62 Fed. Reg. 35821 (July 2, 1997) (listing the original Oct. 11, 1996 PMA approval for the DROMOS DR/DR-A and DROMOS SR/SR-B Cardiac Pacing Systems); www.accessdata.fda.gov/scripts/cdrh/cfPMA/pma.cfm? start_search= 1&PMANumber=P950037&SupplementType=NONE (last updated Feb. 23, 2012 (listing the Oct. 11, 1996 original PMA approval for the DROMOS DR/DR-A AND DROMOS SR/SR-B Cardiac Pacing Systems, PMA No. 950037, and links to the original approval letter and all applicable supplements, including Supplement No. S048, which lists the Mar. 8, 2007 supplemental PMA approval for the DEXTRUS Model 4136 RV lead)); www.accessdata.fda.gov/scripts/cdrh/dfdocs/ cfPMA/pma.cfm?start_search= 1&PMANumber=N970003 &SupplementType=NONE (last updated Feb. 23, 2015) (listing links to the original approval letter PDP No, 970003); and #4, Ex. A) copy of the approval letter for PDP Supplement No. S132, which lists the approval of the Model K063 at issue)). *See also Funk v. Stryker Corp.*, 873 F. Supp. 2d 522, 530-31 (S.D. Tex. 2009)(court may take judicial notice of PMA process under Rule 12(b)(6))(*citing Norris v. Hearst Trust*, 500 F.3d 454, 461 n. 9 (5th Cir. 2007)), *aff'd*, 631 F.3d 777 (5th Cir. 2011). The two process are considered of equal import. *Betterton*, 351 F. Supp. 2d at 534, *citing* 21 U.S.C. § 360e(f)(1)(when a device receives notice of completion of testing in accordance with PDP, it is considered to have PMLA approval); 21 C.F.R. § 870.3610(Date PMA or notice of completion of PDP is required "for implantable pacemaker pulse generator"); 21 C.F.R. 814.19 ("A class III device for which a product development protocol has been declared completed by the FDA under this chapter will be considered to have an approved PMA.").

Class III medical devices approved through the FDA's PMA and PDP processes receive the most federal oversight by the FDA. *Riegel*, 552 U.S. at 317. Usually a device is

classified as III where it cannot be shown that "a less stringent classification would provide reasonable assurance of safety and effectiveness, and the device is 'purported or represented to be for a use in supporting or sustaining human life or for a use which is of substantial importance in preventing impairment of human health,' or 'presents a potential unreasonable risk of illness or injury.'" *Id., citing* § 360c(a)(1)(C)(ii).

Those Class III devices approved by PMA are automatically deemed to meet the "federal requirements" prong for purposes of preemption. *Riegel*, 552 U.S. at 322-23; *Bass*, 669 F.3d at 507; *Rodriguez*, 597 Fed. Appx. at 228. Once a device has received PMA approval, it "must be made with almost no deviations from the specifications in its approval application, for the reason that the FDA has determined that the approved form provides a reasonable assurance of safety and effectiveness." *Riegel*, 552 U.S. at 323. Furthermore, once a device "has been approved through the PDP process [it] 'shall be considered as having [PMA] approval.'" *Rodriguez*, 597 Fed. Appx. at 229, *citing* 21 U.S.C. § 360e(f)(1) and 21 C.F.R. § 814.19. If a plaintiff establishes that the device received PDP approval, which shows there are federal requirements for the device, his "claims survive preemption only if his state claims parallel the federal requirements." *Id.* "To the extent that a plaintiff can show that the FDA-approved processes and procedures were not followed and that the injury was caused by this deviation, the plaintiff's claim will be parallel. However, if the plaintiff challenges the suitability of the precise processes or procedures chosen by the maker, and approved by the FDA, to achieve the broader regulative goals, such a claim could not proceed." *Bass*, 669 F.3d at 512.

In *Riegel*, where a Class III balloon catheter burst during surgery, the patient/plaintiff alleged common law claims of breach of implied warranty, strict liability, negligent design, labeling, marketing, inspection and testing. The Supreme Court concluded that

because the device had undergone PMA, it automatically satisfied the first prong for preemption, i.e., whether the federal government has established safety-related requirements applicable to the particular Medtronic catheter, because PMA "*is* federal safety review" of the device and determined that it offers a reasonable assurance of safety and effectiveness, § 360e(d). 552 U.S. at 323; *Lewkut v. Stryker Corp.*, 724 F. Supp. 2d 648, 653-54 (S.D. Tex. 2010). Regarding the second prong, for those devices that have PMA approval, whether the state-law claims constitute requirements "different from, or in addition to" the federal requirements, the high court in *Riegel* cited its earlier opinion in *Medtronic, Inc. v. Lohr*, 518 U.S. 470 (1996), in which five Justices (O'Connor, joined by Rehnquist, Scalia and Thomas at p. 512, with Breyer concurring at pp. 503-05) determined that common-law causes of action for negligence and strict liability, because safety and effectiveness were the subject of these common law claims, do impose "requirements" that would be preempted by federal requirements specific to the medical device. *Id.* at 323-27. While Justice Ginsburg in a dissent objected that it is "difficult to believe that Congress would, without comment, remove all means of judicial recourse" for plaintiffs who were injured by devices which passed PMA review, the majority opinion opined, "It is not our job to speculate upon congressional motives. If we were to do so, however, the only indication available--the text of the statute--suggests that the solicitude for those injured by FDA-approved devices, which the dissent finds controlling, was overcome in Congress's estimation by solicitude for those who would suffer without new medical devices if juries were allowed to apply the tort law of 50 States to all innovations." *Riegel*, 552 U.S. at 326.

Court's Ruling

The Court agrees with Defendants that as a matter of law Stanfield's state-law claims are all preempted. Because the pacemaker and the lead were Class III devices approved

as safe and effective by the FDA during the PMA process, which imposes device-specific federal requirements, Stanfield's claims for strict liability, breach of implied warranty, and negligent design, testing, labeling, marketing, and sale of these devices are preempted under *Riegel*. *Funk*, 673 F. Supp. 2d at 531. *See, e.g. Martin v. Medtronic, Inc.*, 254 F.3d 573, 575, 585 (5th Cir. 2001) (holding that state product liability tort claims, including defective design, failure warn, and inadequate labeling, are preempted because the PMA process covers these areas and state law imposes requirements different from and in conflict with the PMA process), *cert. denied*, 534 U.S. 1078 (2002); *Scott v. Pfizer, Inc.*, 249 F.R.D. 248, 253-54 (E.D. Tex. 2008). Stanfield does not allege that his state-law claims are parallel to the federal requirements of the PMAs. Nor does he claim that the Defendants' devices did not meet the specifications established the the PMA or did not follow the approved process and procedures.

As for Rule 12(b)(6), Stanfield's Original Petition is completely bare bones, with no factual support, and only legal conclusions that fail to state a claim for which leave may be granted.

Not only has Stanfield failed to respond to the motion to dismiss, but he also has not moved for leave to amend to attempt to state a claim. Nor, as noted, have any of his allegations suggested that he has a claim that would escape preemption. Therefore the Court

ORDERS that Defendants' motion to dismiss is GRANTED with prejudice.

SIGNED at Houston, Texas, this 30th day of September, 2015.

MELINDA HARMON
UNITED STATES DISTRICT JUDGE